

JUL 11 2000

Pharmacia & Upjohn Company  
Attention: Cynthia J. Blanchard  
Regulatory Manager  
7000 Portage Road  
Kalamazoo, MI 49001

Dear Ms. Blanchard:

Please refer to your supplemental new drug application dated January 11, 2000, received January 13, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Genotropin (somatropin [rDNA origin] for injection).

This "Changes Being Effected in 30 days" supplemental new drug application provides for a correction to the gauge size of the needle provided with the product, Genotropin MINIQUICK.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (device instructions for use submitted January 11, 2000). Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Crystal King, P.D., M.G.A., Regulatory Project Manager, at (301) 827-6423.

## Instructions for Use

### Important Note

Please read these instructions completely before using the GENOTROPIN MINIQUICK. If there is anything you do not understand or cannot do, call the toll-free number listed at the end of this leaflet.

If you have any questions about your dose or your treatment with GENOTROPIN, call your healthcare provider right away.

**Use this device only for the person for whom it was prescribed.**

GENOTROPIN MINIQUICK is a device used to mix and administer a single dose of GENOTROPIN Lyophilized Powder (somatropin [rDNA origin] for injection).

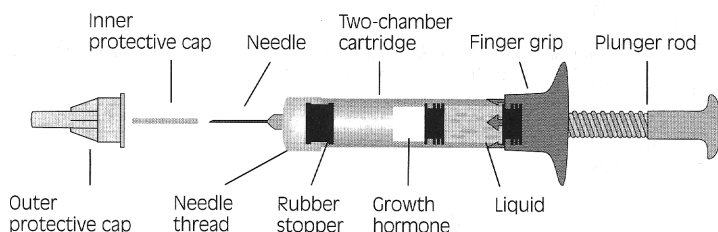
Each GENOTROPIN MINIQUICK comes preloaded with a two-chamber cartridge of GENOTROPIN. GENOTROPIN MINIQUICK is available in ten different dose sizes. **BE SURE YOU HAVE THE DOSE YOUR DOCTOR PRESCRIBED.**

The GENOTROPIN MINIQUICK is disposable; after you administer the dose, you throw the empty unit away.

**IMPORTANT** - always dispose of the GENOTROPIN MINIQUICK properly, as directed by your healthcare provider.

### Components

This system consists of the delivery device, the two-chamber cartridge of GENOTROPIN packaged inside it, and a separate injection needle. The diagram below identifies the different components.



A needle for injection is provided with each device. If you need additional needles, ask for Becton Dickinson Ultra-Fine pen needles, either 29 or 30 gauge.

The two-chamber cartridge of GENOTROPIN contains the growth hormone powder in one chamber and a liquid in the other. When you turn the plunger rod clockwise, the GENOTROPIN MINIQUICK automatically mixes the growth hormone powder and the liquid.

### Storage

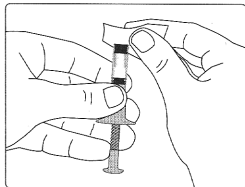
Before the drug is reconstituted (the powder mixed with the liquid), you can store the GENOTROPIN MINIQUICK at room temperature (77° F or less) for up to three months. Keep it in the carton to protect it from light.

You should inject the GENOTROPIN right after you reconstitute it. If that is not possible, you can keep the GENOTROPIN MINIQUICK in the refrigerator (in the carton) for up to 24 hours after reconstitution. Do not freeze. If you do not use the GENOTROPIN MINIQUICK within 24 hours after reconstitution, throw it away.

### Single Use

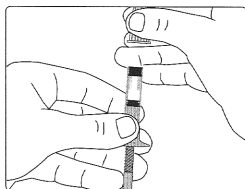
There are no preservatives in the GENOTROPIN MINIQUICK.

**USE EACH GENOTROPIN MINIQUICK ONLY ONCE AND THEN THROW IT AWAY.**

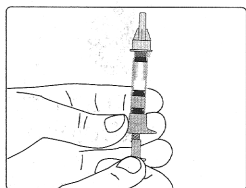


**To help prevent infection, always wash your hands thoroughly with soap and water before using the GENOTROPIN MINIQUICK.**

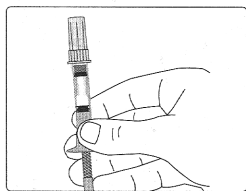
1. Wipe the rubber stopper on the GENOTROPIN MINIQUICK with a pad or swab moistened with rubbing alcohol.



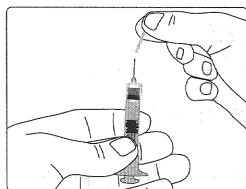
2. Peel the paper covering from the back of the injection needle. Leave both protective caps (inner and outer) on the needle. Screw the needle onto the GENOTROPIN MINIQUICK, turning it until it stops.



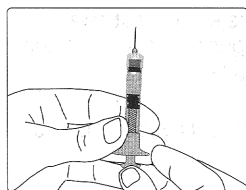
3. Hold the GENOTROPIN MINIQUEICK with the needle pointing upwards.  
**Turn the plunger rod clockwise** until it will go no further to mix the growth hormone powder and diluent.



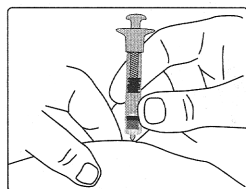
4. **DO NOT SHAKE** the GENOTROPIN MINIQUEICK, as that may inactivate the growth hormone.  
 Check to make sure the solution is clear, indicating that the growth hormone powder is completely dissolved. If you see particles, or if the solution is discolored, **DO NOT INJECT IT**. Instead, call the toll-free number listed at the end of this leaflet.



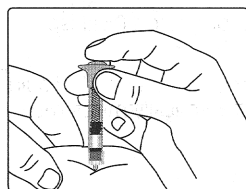
5. Select and disinfect an appropriate injection site, as instructed by your healthcare provider.  
 Remove both the outer and inner protective caps from the needle.



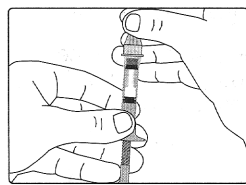
6. Hold the GENOTROPIN MINIQUEICK with the needle pointing upwards.  
 Gently tap the side of the GENOTROPIN MINIQUEICK to move any air bubbles to the top.  
 Push the plunger rod slowly until a drop of liquid appears at the needle point.



7. Pinch a fold of skin at the injection site firmly, and push the needle into the skinfold at a 90-degree angle.



8. Push the plunger rod as far as it will go, to inject the entire contents of the GENOTROPIN MINIQUEICK.  
 Wait a few seconds to ensure that all the growth hormone has been injected. Then, withdraw the needle.



9. After injection, **CAREFULLY** replace the outer protective cap on the needle, and discard the GENOTROPIN MINIQUEICK in a suitable container.  
**Always dispose of the GENOTROPIN MINIQUEICK properly, as instructed by your healthcare provider.**

**Questions about how to use the GENOTROPIN MINIQUEICK?**  
 Call Pharmacia & Upjohn Company toll-free at (800) 645-1280

Manufactured for:  
 Pharmacia & Upjohn Company  
 Kalamazoo, MI 49001, USA

By:  
 Pharmacia & Upjohn AB  
 Stockholm, Sweden